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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/050,768	01/16/2002	Shen-Chun Kuo	CD01352	7782

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SCHERING-PLOUGH CORPORATION  
PATENT DEPARTMENT (K-6-1, 1990)  
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EXAMINER

BALASUBRAMANIAN, VENKATARAMAN

ART UNIT PAPER NUMBER

1624

DATE MAILED: 05/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

10/050,768

**Applicant(s)**

KUO, SHEN-CHUN

**Examiner**

Venkataraman Balasubramanian

**Art Unit**

1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 23 February 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-10 and 13-24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 10 and 13-24 is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☒ Claim(s) 9 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/14/2003, which included amendment to claims 3, 10, and cancellation of claims 11-12, 25-28, has been entered.

Claims 1-10 and 13-24 are now pending.

In view of applicants' response, all 112 second paragraph rejections made in the previous office action have been obviated. In addition, in view of applicants' amendment to claim 10, prior art rejections over Wang et al. and Chabala et al. have been deemed as obviated.

However, the following remains:

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-8 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for  $\text{Bu}_4\text{I}/\text{H}_5\text{IO}_6$  as oxidizing/cyclizing agent, does not reasonably provide enablement for any or all oxidizing/cyclizing agent generically

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embraced in the claim language. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. This rejection is same as made in the previous office action. To repeat:

In evaluating the enablement question, following factors are considered. Note In re Wands, 8 USPQ2d 1400 and Ex parte Forman, 230 USPQ 546. The factors include: 1) The nature of the invention, 2) the state of the prior art, 3) the predictability or lack thereof in the art, 4) the amount of direction or guidance present, 5) the presence or absence of working examples, 6) the breadth of the claims, and 7) the quantity of experimentation needed.

1. The nature of the invention and the state of the prior art:

The invention is drawn to a process of making tetrazinone compound of generic formula IA wherein the compound of formula II is treated with an oxidizing/cyclizing agent to obtain compound of formula IA. Specification is not adequately enabled as to how to make these compounds with an oxidizing/cyclizing agent other than Bu4I/H<sub>5</sub>IO<sub>6</sub>. Claim language as recited reads on any or all known oxidizing agent/cyclizing agent for which there is no corresponding enabling disclosure. Specification on page recites several agents which are known in literature as oxidizing agent but prior art search of these oxidizing agents do not teach them as oxidizing/cyclizing agents. Compound of formula II has more than one reactive site for oxidizing/cyclizing agent and can show propensity to react with the oxidizing agent. Besides the amino of the hydrazine group, there is an amino group in the

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imidazole ring, on the amide group, in addition to a double bond bearing nitrogen.

There is no prior art which suggests that all these groups would be inert to any or all oxidizing agent generically embraced in the claim language.

2. The predictability or lack thereof in the art:

Prior art search in the related area does not suggest how to make these compounds by using the hydrazine II as intermediate with variety of oxidizing agents. Hence the process as applied to the above-mentioned compounds using an oxidizing/cyclizing agent generically claimed by the applicant is not an art-recognized process and hence there should be adequate enabling disclosure in the specification with working example(s).

4. The amount of direction or guidance present:

Examples illustrated in the experimental section or written description offer no guidance or teachings as to how perform the process of making the said tetrazines using different oxidizing/cyclizing agent.

5. The presence or absence of working examples:

Although there is a single example shown in the specification it is limited to  $\text{Bu}_4\text{I}/\text{H}_5\text{IO}_6$  as an oxidizing/cyclizing agent. There are no representative examples of other oxidizing/cyclizing agent given the fact that there are more than one amino group and nitrogen atom in the compound of formula II., which may also undergo oxidation if not cyclization.

6. The breadth of the claim:

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Specification has no support, as noted above, for use of any or all oxidizing/cyclizing agent generically embraced in the claim language that would lead to desired compound of formula I with said reactive amino groups and there is also no valid chemical reasoning for one trained in the art to expect that all these functional groups would be inert toward oxidizing/cyclizing reaction conditions. Note the prior art cited in the Information Disclosure Statement clearly shows reactivity of 5-amino group in the imidazole ring.

7. The quantity of experimentation needed:

The quantity of experimentation needed would be an undue burden on skilled art in the chemical art since there is inadequate guidance given to the skilled artisan for the many reasons stated above. Even with the undue burden of experimentation, there is no guarantee that one would get the product of desired structure, namely compound of formula I embraced in the instant claims in view of the prior art teachings.

Thus, factors such as "sufficient working examples", the "level of skill in the art and predictability, etc. have been demonstrated to be sufficiently lacking in the case for the instant claims.

Claims 1-8 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for Bu<sub>4</sub>I as soluble iodide, does not reasonably provide enablement for any or all iodide generically embraced in the claim language. The specification does not enable any person skilled in the art to which it pertains, or

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with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The following apply:

The scope of the claim as recited include any or all iodide for which there is no enabling disclosure. Applicants are asserting in the specification that the iodide functions as catalyst for the reaction and therefore the iodide is a critical limitation for the process. Without knowing what iodide is included or excluded, one need to extensive experimentation to arrive at a suitable iodide given the fact that solubility of iodide would also to be considered in the choice of the iodide. Prior art does not teach how to select an iodide suitable for the instant reaction scheme and the example recited in the specification is limited to  $\text{Bu}_4\text{NI}$  which is known to be soluble in organic solvent. Hence the specification is not adequately enabled to make the product of formula I with iodide other than  $\text{Bu}_4\text{NI}$ .

Applicants' traversal as noted in the Advisory Action is not persuasive. To restate: Contrary to applicants urging, these are process claims and mere recitation that "oxidation/cyclization agent" is not sufficient for the enablement requirement. There is no evidence in the specification or in the prior art that any or all oxidation/cyclization can be used for the said reaction. Without any guidance in the specification, one trained in the art had to conceive and experiment to arrive at a suitable oxidation/cyclization agent. The same applies to the second rejection. Without any guidance, one trained in the art has to identify which iodide would work which would not by experimentation.

In both cases the finding would be not applicants' teaching.

Hence these rejections are proper and are maintained.

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***Allowable Subject Matter***

Claim 9 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims. Claims 10 and 13-24 are allowed. Said claim would be allowed since specific process embraced in these claims are not taught or suggested by the art of record or from a search in the relevant art area.

**Conclusion**

Any inquiry concerning this communication from the examiner should be addressed to Venkataraman Balasubramanian (Bala) whose telephone number is (571) 272-0662. The examiner can normally be reached on Monday through Thursday from 8.00 AM to 6.00 PM. The Supervisory Patent Examiner (SPE) of the art unit 1624 is Mukund Shah whose telephone number is (571) 272-0674. If Applicants are unable to reach Mukund Shah within 24-hour period, they may contact James O. Wilson, Acting-SPE of art unit 1624 at 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned (703) 872-9306. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

  
Venkataraman Balasubramanian

4/30/2004